201 KAR 2:310. Compounding for a practitioner's office or institutional administration.

RELATES TO KRS 315.191(1)(a).
STATUTORY AUTHORITY: KRS 315.191(1)(a)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) requires the board to promulgate administrative regulations to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, and pharmacies. This administrative regulation addresses compounding for use by a practitioner's office administration or institutional administration.

Section 1. A pharmacist, pharmacist intern, or pharmacy technician may prepare a compounded drug for a practitioner's office administration or institutional administration.

Section 2. A compounded drug that contains a controlled substance shall not be compounded for office or institutional administration.

Section 3. The pharmacist shall receive a written, verbal, facsimile, or electronic request for a compounded drug from a practitioner, indicating the formulation, strength, and quantity ordered.

Section 4. Label Requirements. A label shall be generated for the compounded drug and shall include:
(1) The name of the practitioner;
(2) The designated name and strength of the compounded drug;
(3) The quantity dispensed;
(4) A lot or batch number of the compounded drug;
(5) The beyond use date for the compounded drug;
(6) The date the compounded is dispensed;
(7) The pharmacy's name, address, and telephone number;
(8) Any special storage requirements;
(9) A notation stating "For Office or Institutional Administration Only-Do Not Dispense to Patient;
(10) Any auxiliary label required for the compounded drug.

Section 5. The compounded drug shall be administered in the practitioner's office or institution and shall not be dispensed to the patient.

Section 6. The prescription for the compounded drug shall be kept pursuant to 201 KAR 2:170. (35 Ky.R. 1954; 2006; eff. 3-11-09.)